

**REMARKS****I. Status of the claims**

Claim 1 and 2 are amended.

Claims 1-3, 17-19, and 21-22 are pending.

Claims 4-16 and 20 are withdrawn.

**II. An Expert Declaration is Submitted to Show that the Teaching of Regenmortel Does Not Satisfy the Legal Criteria for Anticipation**

As the Interview Summary sent by the examiner reiterates, Regenmortel does **not** teach all the elements of claim 1.

Applicant is dismayed that even after the extensive interview of April 21, 2004 in which the examiner, SPE Le, the inventor, Mr. Lazarus and the undersigned representing the applicant, discussed why Regenmortel does not teach all the claimed elements and does not satisfy the legal requirement for an anticipation rejection, the examiner persists in maintaining this rejection.

A Declaration under 37 C.F.R. § 1.132 by Dr. Byron Anderson, an expert in the field of immunology, is appended as Exhibit A. His Curriculum Vitae is Exhibit B. As Dr. Anderson testifies, mimotopes as reviewed by Regenmortel, "are not proteins or peptide sequences derived from proteins" (Exhibit A, par. 4a) (any homology of a mimotope sequence to a protein sequence is by chance only). Furthermore, Dr. Anderson testifies that the mimotopes of Regenmortel "cannot be defined as a comparative protein as the examiner has done...." (Exhibit A, par. 4a)

Dr. Anderson testifies that the present invention is "unique and inventive", (Exhibit A, par. 4b) and is "a contribution to the field of immunology". (Exhibit A, page 6)

Regenmortel expressly defines his review as of the:

Steadily increasing ability to identify antigenic sites in viral proteins and then to design linear peptides that mimic the three-dimensional conformational features of key immunodominant sites in viral proteins.

Note that mimotopes are synthetic peptides designed to minimize a 3-D composition. Claim 1 is not limited to synthetic peptides, which, according to the examiner, is taught in Regenmortel (Action page 2, par. 2).

All claims in the present application relate to claim 1. Claim 1 is amended herein for clarity, but the elements are the same as original claim 1. The examiner's attempts to force parts of

Regenmortel into a shoe that doesn't fit, *i.e.*, claim 1, is illustrated below and testified to by Dr. Anderson (Exhibit A):

Elements of Claim 1	The Examiner's Selections from Regenmortel (Action pages 2-3)
immunogenic peptide	mimotopes, mimotope 13
target protein	viral protein, HbsAg, HCV35-47
comparative protein	mimotopes, HCV, mimotope 17, 14 or P715c

There are target proteins, immunogenic peptides with a portion of the target protein sequence, and comparative proteins in claim 1.

In contrast, Regenmortel only has "mimotopes" and viral antigens. There is no correspondence with the three elements of claim 1. "Mimotopes" are used for two separate elements of claim 1. Therefore, by definition Regenmortel does not anticipate claim 1.

The examiner relates his mimotopes both to "peptides" and to "comparative proteins". In the example given on page 3, "HbsAg" is the target, HCV the "comparative protein"

The examiner equates "HCV 35-47 to a target protein and mimotope 17 or mimotope 14 as a comparative protein. (According to the examiner a "comparative protein" is a "non-target protein having less than 50% homology") as well as designating "mimotope 13" as a "peptide" but this mimotope is not derived from a target protein.

If the examiner thinks mimotopes are analogous to claim 1's "target protein", that would teach **away** from the present invention because the peptides of claim 1 **expressly** show sequence similarity to a target protein, whereas the mimotopes of Regenmortel by definition show dissimilar sequences.

The examiner misreads the claimed application because the comparative proteins are compared with the "immunogenic peptides" not to the target proteins [(see claim 1(c))]. The comparative proteins are **NOT CLAIMED**. The preamble clearly defines "peptides" as the claimed composition.

The court in *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332 stated:

"In general, a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1784 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). "[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention. See, e.g., *Electro Sci. Indus. v. Dynamic Details, Inc.*, 307 F.3d 1343, 1348, 64 USPQ2d 1781, 1783 (Fed. Cir. 2002); *Rapoport v. Dement*, 254 F.3d 1053, 1059, 59 USPQ2d 1215, 1219 (Fed. Cir. 2001); *Pitney Bowes*, 182 F.3d at 1306, 51 USPQ2d at 1166. On the other hand, "if the body of the claim sets out the complete invention," then the language of the preamble may be superfluous. *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1310, 64 USPQ2d 1832, 1837 (Fed. Cir. 2002); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1373-74, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001).

The court in *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298 stated:

If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is "necessary to give life, meaning, and vitality" to the claim, then the claim preamble should be construed as if in the balance of the claim. *Kropa v. Robie*, 38 C.C.P.A. 858, 187 F.2d 150, 152, 88 U.S.P.Q. (BNA) 478, 480-81 (CCPA 1951); see also *Rowe v. Dror*, 112 F.3d 473, 478, 42 U.S.P.Q.2D (BNA) 1550, 1553 (Fed. Cir. 1997); *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 U.S.P.Q.2D (BNA) 1962, 1966 (Fed. Cir. 1989).

### **III. Because Rejections Based on Regenmortel are Faulty, Regenmortel Must be Removed as a Basis for the 103 Rejections**

Claims 18-19 were rejected as obvious over Regenmortel and Hasegawa. Claim 22 was rejected as obvious over Regenmortel and Tu.

Because, as shown in Section II herein, and the Declaration Under 1.132 (Appendix A) that Regenmortel does not teach the peptides of the present invention, these rejections fall also.

**IV. Other**

In claim 1, (a) and (b) are combined.

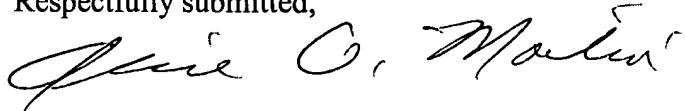
If required, supplemental expert Declarations are available.

**V. Conclusion**

Application requests allowance of pending claims as amended herein.

No fees are believed due at this time, however, please charge any additional deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (21417/92378).

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Alice O. Martin".

Alice O. Martin

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